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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,627	06/19/2006	Heinz Von Der Kammer	2335.0170000/SRL/KPQ	8551

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EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,627	VON DER KAMMER ET AL.	
	Examiner	Art Unit	
	TERESA E. STRZELECKA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 14, drawn to a special technical feature of a method of diagnosing or prognosticating a neurodegenerative disease in a subject, or determining whether a subject is at increased risk of developing said disease, comprising: determining a level and/or an activity of (i) a transcription product of a gene coding for HIF3a, and/or (ii) a translation product of a gene coding for HIF3a, and/or (iii) a fragment, or derivative, or variant of said transcription and/or translation product, in a sample obtained from said subject and comparing said level or said activity, or both said level and said activity of said transcription product and/or said translation product to a reference value representing a known disease status and/or to a reference value representing a known health status, and said level and/or said activity is varied or altered compared to a reference value representing a known health status, and/or is similar or equal to a reference value representing a known disease status, thereby diagnosing or prognosticating said neurodegenerative disease in said subject, or determining whether said subject is at increased risk of developing said neurodegenerative disease.

Group II, claim(s) 3, 17, 18, drawn to a special technical feature of a kit for diagnosing or prognosticating a neurodegenerative disease in a subject, or determining the propensity or predisposition, or the risk of a subject to develop such a disease, said kit comprising: at least one reagent which is selected from the group consisting of (i) reagents that selectively detect a transcription product of a gene coding for HIF3a and (ii) reagents that selectively detect a translation product of a gene coding for HIF3a; whereby the diagnosis or prognosis or determination of the risk to develop said neurodegenerative disease is determined by the steps of (a) detecting in a sample obtained from said subject a level, or an activity, or both said level and said activity of a transcription product and/or of a translation product of a gene coding for HIF3a, and (b) comparing said level or activity, or both said level and said activity of a transcription product and/or of a translation product of a gene coding for HIF3a to a reference value representing a known health status and/or to a reference value representing a known disease status, and said level, or activity, or both said level and said activity, of said transcription product and/or said translation product is varied compared to a reference value representing a known health status, and/or is similar or equal to a reference value representing a known disease status.

Group III, claim(s) 4-7, 19-22, drawn to a special technical feature of a genetically altered non-human animal comprising a non-native gene sequence coding for HIF3a, or a fragment, or a derivative, or a variant thereof.

Group IV, claim(s) 8, 23, drawn to a special technical feature of a method of developing diagnostics and therapeutics to treat neurodegenerative diseases, comprising screening, testing, or validating compounds, agents, and modulators using the genetically altered non-human animal according to claim 4.

Group V, claim(s) 9, drawn to a special technical feature of a modulator of an activity and/or of a level of at least one substance which is selected from the group consisting of (i) a gene coding for HIF3a, (ii) a transcription product of a gene coding for HIF3a, (iii) a translation product of a gene coding for HIF3a, and (iv) a fragment, or derivative, or variant of (i) to (iii).

Group VI, claim(s) 10, 15, 24, drawn to a special technical feature of a method for screening for a modulator of neurodegenerative diseases, or related diseases or disorders of one or more substances selected from the group consisting of (i) a gene coding for HIF3a, (ii) a transcription product of a gene coding for HIF3a, (iii) a translation product of a gene coding for HIF3a, and (iv) a fragment, or derivative, or variant of (i) to (iii), said method comprising: (a) contacting a cell with a test compound; (b) measuring the activity and/or level of one or more substances recited in (i) to (iv); (c) measuring the activity and/or level of one or more substances recited in (i) to (iv) in a control cell not contacted with said test compound; and (d) comparing the levels and/or activities of the substance in the cells of step (b) and (c), wherein an alteration in the activity and/or level of substances in the contacted cells indicates that the test compound is a modulator of said diseases or disorders.

Group VII, claim(s) 11, 12, 25, 26, drawn to a special technical feature of a method of screening for a modulator of neurodegenerative diseases, or related diseases or disorders of one or more substances selected from the group consisting of (i) a gene coding for HIF3a, (ii) a transcription product of a gene coding for HIF3a, (iii) a translation product of a gene coding for HIF3a, and (iv) a fragment, or derivative, or variant of (i) to (iii), said method comprising: (a) administering a test compound to a test animal which is predisposed to developing or has already developed symptoms of a neurodegenerative disease or related diseases or disorders in respect of the substances recited in (i) to (iv); (b) measuring the activity and/or level of one or more substances recited in (i) to (iv); (c) measuring the activity and/or level of one or more substances recited in (i) to (iv) in a matched control animal which is predisposed to developing or has already developed symptoms of a neurodegenerative disease or related diseases or disorders in respect to the substances recited in (i) to (iv) and to which animal no such test compound has been administered; (d) comparing the activity and/or level of the substance in the animals of step (b) and (c), wherein an alteration in the activity and/or level of substances in the test animal indicates that the test compound is a modulator of said diseases or disorders.

Group VIII, claim(s) 13, 27, drawn to a special technical feature of an assay for testing a compound or a plurality of compounds to determine the degree of binding of said compounds to a HIF3a translation product, or to a fragment, or derivative, or variant thereof, said assay comprising the steps of: (i) adding a liquid suspension of said HIF3a translation product, or a fragment, or

derivative, or variant thereof, to a plurality of containers; (ii) adding a detectable compound or a plurality of detectable compounds to be screened for said binding to said plurality of containers; (iii) incubating said HIF3a translation product, or said fragment, or derivative, or variant thereof, and said detectable compound or compounds; (iv) measuring amounts of detectable compound or compounds associated with said HIF3 a translation product, or with said fragment, or derivative, or variant thereof; and (v) determining the degree of binding by one or more of said compounds to said HIF3a translation product, or said fragment, or derivative, or variant thereof.

Group IX, claim(s) 16, 28, drawn to a special technical feature of a method for detecting the pathological state of a cell in a sample obtained from a subject, comprising immunocytochemical staining of said cell with an antibody specifically immunoreactive with an immunogen, wherein said immunogen is a translation product of a gene coding for HIF3a, SEQ ID NO. 2, SEQ ID NO. 3, SEQ ID NO. 4, SEQ ID NO. 5, or a fragment, or derivative, or variant thereof, wherein an altered degree of staining, or an altered staining pattern in said cell compared to a cell representing a known health status indicates a pathological state of said cell which relates to a neurodegenerative disease.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Makino et al. (J. Biol. Chem., vol. 277, pp. 32405-32408, 2002; cited in the IDS) teach primers for the amplification of the HIF3a transcription products (page 32407, first paragraph), therefore they teach a reagent for selective detection of HIF3a transcription products. Therefore the claims do not represent a contribution over prior art, and thus a unifying special technical feature.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

SEQ ID NO: 1, 2, 3, 4 or 5 (claims 14-16, 18 and 26).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 3, 10, 11 and 16.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they are drawn to proteins with different structures and functions.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable

product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
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Primary Examiner, Art Unit 1637

May 13, 2008